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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 314

[Docket No. 85N–0214]

Court Decisions, ANDA Approvals, and 180–Day Exclusivity

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim rule; opportunity for public comment.

SUMMARY: The Food and Drug Administration (FDA) is issuing an interim rule to amend its regulations governing the definition of court decisions that affect the timing of certain abbreviated new drug application (ANDA) approvals and the beginning of 180-day exclusivity under the Federal Food, Drug, and Cosmetic Act (the act). The interim rule eliminates the current definition of the court decision. This change is necessitated by recent court decisions on these issues.

DATES: This interim rule is effective [*insert date 5 days after date of publication in the* **Federal Register**]. Submit written comments by [*insert date 90 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Virginia G. Beakes, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

NPR 3

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the Hatch-Waxman Amendments) amended the act. The Hatch-Waxman Amendments created section 505(j) of the act (21 U.S.C. 355(j)), which established the ANDA approval procedures. These procedures allow for the approval and marketing of lower priced generic drug products through a process that includes, among other elements, a listing of innovator drug patents, a procedure for certification to listed patents and judicial review of patent claims, and a period of 180 days of marketing exclusivity for certain ANDA applicants who challenge innovator patents.

FDA's interpretation of two provisions of section 505(j) of the act have been affected by recent court decisions interpreting the phrase ''decision of a court'' or ''court decision.'' Section 505(j)(5)(B)(iii) of the act governs the approval of ANDA's when a patent owner or new drug application (NDA) holder has brought a timely patent infringement action in response to an ANDA applicant's notice of filing of a paragraph IV certification to a listed patent. Section 505(j)(5)(B)(iv) of the act governs the eligibility for and timing of 180-day exclusivity. The regulations implementing these statutory provisions are found in § 314.107 (21 CFR 314.107). Certain aspects of these regulations have been successfully challenged in *TorPharm, Inc.*, v. *Shalala*, No. 97–1925, 1997 U.S. Dist. LEXIS 21983 (D.D.C. Sept. 15, 1997), appeal withdrawn and remanded, 1998 U.S. App. LEXIS 4681 (D.C. Cir. Feb. 5, 1998); vacated No. 97–1925 (D.D.C. Apr. 9, 1998); and *Mylan Pharmaceuticals, Inc.*, v. *Shalala*, No. 99–2995, slip op. (D.D.C. Jan. 4, 2000). In response to this litigation, FDA is issuing this interim rule withdrawing from § 314.107 the definitions related to court decisions.

The statutory provisions at issue in the *TorPharm* and *Mylan* cases apply the concept of a court decision to the timing of certain ANDA approvals and to the start of 180-day exclusivity. There is a 30-month statutory bar to approval of an ANDA that is the subject of patent infringement litigation except if ''before the expiration of such period the court decides that such patent is invalid or not infringed, the approval will be made effective on the date of the *court decision*''

(section 505(j)(5)(B)(iii)(I) of the act (emphasis added)). In implementing this provision in current § 314.107(e)(1), FDA interpreted ''court'' to mean ''the court that enters final judgment from which no appeal can be or has been taken.'' The agency's reasons for adopting this interpretation are discussed in the preambles to the proposed and final rules implementing the 1984 Drug Price Competition and Patent Term Restoration Act (54 FR 28872 at 28893 through 28895, July 10, 1989, and 59 FR 50338 at 50352 through 50354, October 3, 1994).

Certain court decisions are also important for 180-day generic drug exclusivity. FDA's interpretation of ''court'' in the court decision described in section 505(j)(5)(B)(iii)(I) of the act was influenced by the role such a decision plays in 180-day exclusivity. The 180-day period of exclusivity can begin on either: (1) The date of first commercial marketing; or (2) ''the date of a *decision of a court* * * * holding the patent which is the subject of the [paragraph IV] certification to be invalid, or not infringed, whichever is earlier'' (section 505(j)(5)(B)(iv) of the act (emphasis added)). As described in the preambles to the implementing regulations (54 FR 28893 through 28895, and 59 FR 50352 through 50354), FDA believed that for the 180-day exclusivity to have real meaning for the eligible ANDA the court decision triggering the exclusivity must be the one that finally resolves the patent infringement litigation related to the ANDA. Therefore, for purposes of section 505(j)(5)(B)(iv) of the act, FDA determined that ''court'' means ''the court that enters final judgment from which no appeal can be or has been taken,'' as stated in current § 314.107(e)(1).

FDA's interpretation of the term ''court'' has been successfully challenged in the context of both the timing of ANDA approvals and the commencement of 180-day exclusivity. In *TorPharm* v. *Shalala*, the D.C. District Court found FDA's interpretation not supported by the statute and directed FDA to approve an ANDA upon a decision of the district court finding a patent invalid, unenforceable, or not infringed. When the case became moot, FDA's appeal of that decision was withdrawn, and the district court opinion was vacated. In the period since the *TorPharm* decision, FDA has continued to apply the definition of ''court'' set out at § 314.107(e).

Recently, in *Mylan Pharmaceuticals, Inc.*, v. *Shalala*, the D.C. District Court found FDA's interpretation of court as used in the 180-day exclusivity context inconsistent with the statute's plain meaning. However, the court also determined that the applicant who relied in good faith on FDA's interpretation of the 180-day exclusivity provision should not be punished by losing its exclusivity. The court therefore refused to order FDA to begin the running of 180-day exclusivity upon the decision of the district court in the patent litigation at issue.

These recent decisions add considerable uncertainty to FDA's implementation of the ANDA approval and 180-day generic drug exclusivity programs. These regulatory programs already have been disrupted by the changes in eligibility for 180-day exclusivity necessitated by *Mova Pharmaceutical Corp.*, v. *Shalala*, 140 F.3d 1060 (D.C. Cir. 1998), and *Granutec, Inc.*, v. *Shalala*, 46 U.S.P.Q.2d 1398 (4th Cir. 1998). Therefore, in determining its response to the *TorPharm* and *Mylan* decisions, a primary concern for the agency has been to identify an approach that will minimize further disruption and provide the regulated industry with reasonable guidance for making future business decisions.

The government has not appealed the *Mylan* decision and will follow that court's interpretation of the statute in approving ANDA's and calculating the commencement of 180 days of exclusivity. Although the agency believes that the statutory provisions at issue may properly be interpreted as FDA set out in § 314.107(e), the agency nonetheless has determined that because of the confusion and uncertainty created by the repetitive litigation of these issues, it is in the interest of the regulated industry and the agency to accept the interpretation of the *TorPharm* and *Mylan* courts. The agency will incorporate the *TorPharm* and *Mylan* courts' interpretation of the statute into the final rule implementing the changes in 180-day exclusivity proposed in the **Federal Register** of August 6, 1999 (64 FR 42873).

In the period before the final rule implementing changes in 180-day exclusivity is completed, the agency is issuing this interim rule to remove § 314.107(e)(1) through (e)(2)(iii). FDA issued a guidance for industry stating that the agency would continue to apply the interpretation set out

in § 314.107(e)(1) through (e)(2)(iii) in certain circumstances, and that the interpretation urged by the courts would be applied prospectively.[1] This guidance will apply until revoked or revised by the agency.

II. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental impact assessment nor an environmental impact statement is required.

III. Analysis of Impacts

FDA has examined the impacts of the interim rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million or adversely affecting in a material way a sector of the economy, competition, or jobs, or if it raises novel legal or policy issues. The agency believes that this interim rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the interim rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because good cause exists under 5

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[1]Guidance for industry, "Court Decisions, ANDA Approvals, and 180–Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act," March 2000. This guidance is available on the Internet at http://www.fda.gov/cder/guidance/index.htm.

U.S.C. 553(d)(3) for making this interim rule effective in less than 30 days, the agency is not required to analyze regulatory options under the Regulatory Flexibility Act (see 5 U.S.C. 604(a)). Therefore, under the Regulatory Flexibility Act, no further analysis is required.

Section 202(a) of the Unfunded Mandates Reform Act requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation). The elimination of the definition of ''court'' in § 314.107(e)(1) through (e)(2)(iii) will not result in any significant increased expenditures by State, local, and tribal governments or the private sector. The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for the interim rule, because the interim rule is not expected to result in any 1-year expenditure that would exceed $100 million adjusted for inflation. The current inflation-adjusted statutory threshold is $110 million.

This interim rule is intended to bring FDA's regulations into conformance with the *TorPharm* and *Mylan* court decisions. The agency believes that this interim rule is necessary and that: (1) It is consistent with the principles of Executive Order 12866, (2) it is not a significant regulatory action under that Order, (3) an analysis is not required under the Regulatory Flexibility Act, and (4) it is not likely to result in an annual expenditure in excess of $100 million.

IV. Federalism

FDA has analyzed this interim rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the interim rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the interim rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

V. Paperwork Reduction Act of 1995

This interim rule contains no collections of information, and clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (Public Law 104–13) is not required.

VI. Effective Date

The agency is issuing these amendments as an interim rule effective [*insert date 5 days after date of publication in the* **Federal Register**]. This action is being taken to remove the provisions of § 314.107(e)(1) through (e)(2)(iii), which were determined by the *TorPharm* and *Mylan* courts to be unsupported by the act. These decisions have rendered the regulatory provisions unenforceable, and the agency can find no good reasons to retain the provisions in the regulations. For the foregoing reasons, FDA finds, for good cause, that notice and public procedure would be impracticable, unnecessary, and contrary to the public interest. Therefore a public comment period before the establishment of this interim rule may be dispensed with under 5 U.S.C. 553(b)(3)(B) and § 10.40(e)(1) (21 CFR 10.40(e)(1)). In addition, the Commissioner of Food and Drugs finds good cause under 5 U.S.C. 553(d)(3) and § 10.40(c)(4)(ii) for making this interim rule effective in less than 30 days.

VII. Opportunity for Public Comment

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this interim rule, on or before [*insert date 90 days after date of publication in the* **Federal Register**]. FDA will use any comments received to determine whether this interim rule should be modified or revoked. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 314 is amended as follows:

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

1. The authority citation for 21 CFR part 314 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 371, 374, 379e.

2. Section 314.107 is amended by removing paragraphs (e)(1) through (e)(2)(iii); by redesignating paragraph (e)(2)(iv) as paragraph (e); and by revising the heading for newly redesignated paragraph (e) to read as follows:

§ 314.107 Effective date of approval of a 505(b)(2) application or abbreviated new drug application under section 505(j) of the act.

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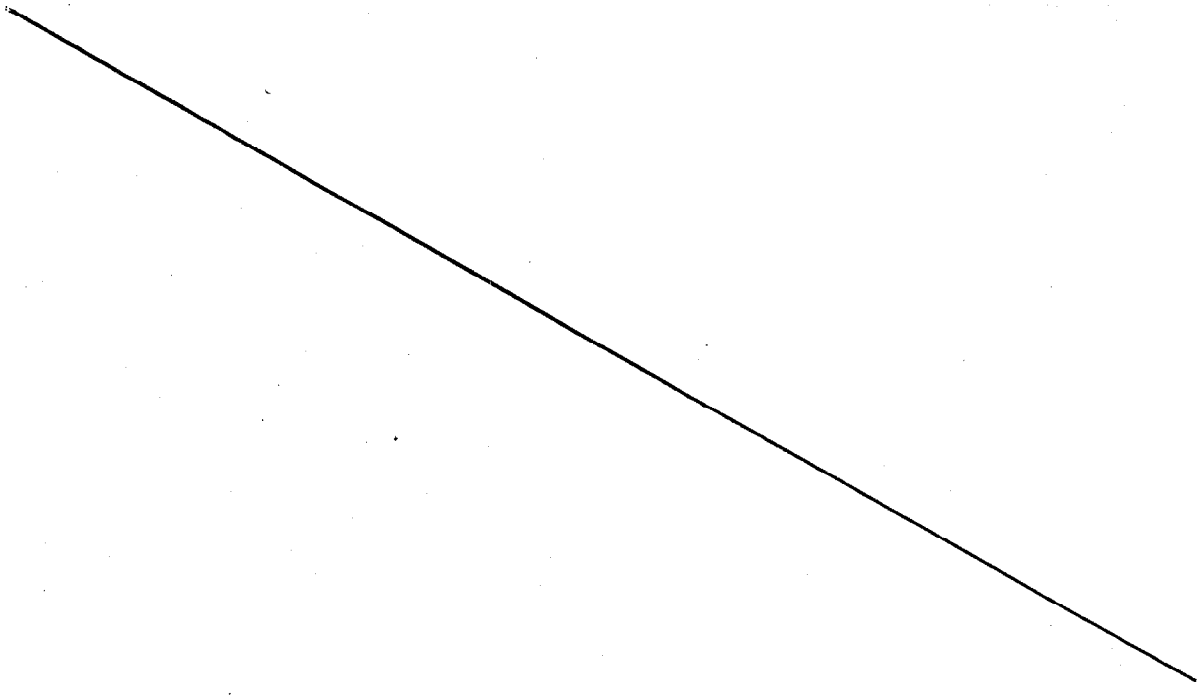

(e) *Notification of court actions.* * * *

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Dated: 6/27/00

June 27, 2000

Margaret M. Dotzel
Associate Commissioner for Policy

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

[FR Doc. 00–???? Filed ??–??–00; 8:45 am]

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